2. REMARKS / DISCUSSION OF ISSUES

Claims 1-19 are pending in the application. Claims 1 and 12 are the independent claims.

Rejections under 35 U.S.C. § 103

Claims 1-19 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious in view of *Hatfield, et al.* (U.S. Patent 5,840,032) and *Lin, et al.* (U.S. Patent 5,957,138). For at least the reasons set forth below, Applicants respectfully submit that all claims are patentable over the applied art.

A *prima facie* case of obviousness has three requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, requires some reason that the skilled artisan would modify a reference or to combine references.[1] The Supreme Court has, however, cautioned against the use of "rigid and mandatory formulas" particularly with regards to finding reasons prompting a person of ordinary skill in the art to combine elements in the way the claimed new invention does.[2] But rather the Supreme Court suggests a broad, flexible "functional approach" to the obviousness analysis recognizing that "[i]n many fields it may be that there is little discussion of obvious techniques or combinations."[3] Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the same time the invention was made. In other words, a hindsight analysis is not allowed.[4] Lastly, the prior art

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[1] See Princeton Biochemicals, Inc. v. Beckman Coulter, Inc., 411 F.3d 1332 (Fed. Cir. 2005) ("[S]imply identifying all of the elements in a claim in the prior art does not render a claim obvious.").

[2] See KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007) ("The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents.").

[3] Id. See also Id. at 1743 F. 3d 1356 (Fed. Cir. 2006) ("Our suggestion test is in actuality quite flexible and not only permits, but *requires*, consideration of common knowledge and common sense") (emphasis in original).

[4] See Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir. 1991) ("Hindsight is not a justifiable basis on which to find that ultimate achievement of a long sought and difficult scientific goal

reference or combination of references must teach or suggest all the limitations of the claims.[5]

i. Claims 1 and 12

Claim 1 recites:

A method of capturing an image using an ultrasound system, comprising:

directing ultrasound waves from the ultrasound system to a body;

surveying the image to collect motion data;

analyzing the motion data to identify a flow in the image, the analyzing comprising segmenting the image into a flow region and a non-flow region;

scanning a limited region of the image containing the flow with a flow imaging technique; and

distinguishing plaque from clutter when low-level echoes are present.

In an embodiment described in the filed application, a plaque/clutter analysis system 28 automatically adjusts the gain of an imaging acquisition system based on whether plaque is present or clutter is present. To this end, for distinguishing plaque from clutter when low level echoes are present in vessel interiors, for example, the motion signals present in the same locations as the low-level echoes can be analyzed. If there is a no flow signal, the low level echoes are likely to be plaque; and if flow is present, the low level echoes are likely to be clutter or reverb.

Hatfield, et al. fails to disclose distinguishing plaque from clutter, and fails to even mention 'plaque' in its disclosure. While the applied art to *Lin, et al.* does disclose the viewing of irregularities such as plaque, there is no disclosure of distinguishing plaque from clutter, and especially when low-level signals are present. For instance, at the paragraph beginning on column 6, line 59, *Lin et al.* discloses:

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was obvious.").

[5] See In re Wilson, 424 F.2d 1382 (C.C.P.A. 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art.").

"The three-dimensional flow structure 400 is shown having an exterior surface 402 and an interior surface 406 which define the flow lumen. As depicted in FIG. 4, the interior surface 406 has an irregular surface 404. For example, the flow structure 400 may represent an artery, vein, or other vessel, and the irregular surface 404 may represent plaque, an intimal defect, etc., in the artery. By providing a three-dimensional image of the flow lumen, and in particular, the flow lumen edge of a flow structure, rather than a solid representation as provided by past ultrasound imaging techniques, such irregular surfaces and other characteristics of the flow lumen, and in particular, the flow lumen edge, may be represented."

Thus, the reference discloses the identification of plaque, but fails to disclose the distinguishing between plaque and clutter as specifically recited in claim 1. Therefore, Applicants respectfully submit that the applied art fails at least one feature of claim 1. As such, a *prima facie* case of obviousness cannot be established from any proper combination of *Hatfield, et a*l. and *Lin, et al.*, and claim 1 is patentable thereover. Furthermore, claims 2-11, which depend immediately or ultimately from claim 1, are patentable for at least the same reasons and in view of their additionally recited subject matter.

Claim 12 recites:

An ultrasound system, comprising:

a survey system for collecting motion data from a target image;

a segmentation system for mapping a region of flow within the image based on the motion data, the segmentation system configured to segment the image into a flow region and a non-flow region;

a flow acquisition system that automatically limits the collection of flow image data within the image to the region of flow; and

a plaque/clutter analysis system configured to distinguish between plaque and clutter.

As noted above, in an embodiment described in the filed application, a plaque/clutter analysis system 28 automatically adjusts the gain of an imaging acquisition system 11 based on whether plaque is present or clutter is present. For distinguishing plaque from clutter when low level echoes are present in vessel interiors, for example, the

motion signals present in the same locations as the low-level echoes can be analyzed. If there is a no flow signal, the low level echoes are likely to be plaque; and if flow is present, the low level echoes are likely to be clutter or reverb. Applicants respectfully submit that neither *Hatfield, et a*l. nor *Lin, et al*. taken alone or in combination disclose a plaque/clutter analysis system so configured to distinguish between plaque and clutter as specifically recited in claim 12.

As such, a *prima facie* case of obviousness cannot be established from any proper combination of *Hatfield, et a*l. and *Lin, et al*., and claim 12 is patentable thereover. Furthermore, claims 13-19, which depend immediately or ultimately from claim 12, are patentable for at least the same reasons and in view of their additionally recited subject matter.

Conclusion

In view the foregoing, applicant(s) respectfully request(s) that the Examiner withdraw the objection(s) and/or rejection(s) of record, allow all the pending claims, and find the application in condition for allowance.

If any points remain in issue that may best be resolved through a personal or telephonic interview, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted on behalf of:

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/William S. Francos/

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Date: June 24, 2010

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